Department of Laboratory Services

Procedure: i-STAT 1 Analyzer Procedure	New Revised Date: 5/18/2023 Termination Date:	POC: i-STAT	Page: 1 of 16

1.0	**Purpose**	This procedure provides instructions for the prioritizing and usage of the i-STAT analyzer. The i-STAT analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood. The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis in the Point of Care setting. A portable handheld analyzer, a cartridge with the required tests, and 2-3 drops of blood permits the caregiver to view quantitative test results for blood gas, chemistry, H and H, and coagulation tests in approximately two minutes. FDA Limitation – PT/INR cartridge is only approved for monitoring Coumadin or Warfarin oral anticoagulant therapy. FDA Limitation – ACT C and ACT K is only approved for patients on Heparin therapy. Refer to i-STAT 1 System Manual for further information.	
2.0	**Scope**	To be used for the administrative and technical operations of Patient Care Services and Laboratory Services for patient testing in Respiratory, Laboratory, and Point of Care Testing. Refer to "POC Testing Site Chart" and to the "Respiratory Testing Site Chart".	
3.0	**Procedure – Supplies, Preparation of Analyzer**		
	Supplies	i-STAT Analyzer i-STAT cartridges Portable Printer, if applicable Quality Assurance Materials (Electronic Simulator, Control Solution, and Calibration Verification Set) Data Management System (i-STAT Downloader, i-STAT Downloader-Recharger, IR link for Portable Analyzer, Data Management system (DE) in Telcor QML, and LIS-HIS Interface Software).	
	Prior to Using Analyzer	Install Batteries	(2) 9-volt lithium batteries, or (1) rechargeable battery Charge Downloader/Recharger (Refer to System Manual if rechargeable batteries and Downloader/Recharger are used.)
		Check Date-Time	Press On/Off Key Check Date-Time at the top of the display are correct (Refer to System Manual)

		Check Software	New analyzers or analyzers that have been repaired and returned or replaced will have standard application software. If a different application software is in use in your facility, it must be installed in new, repaired, or replaced analyzers before they are put into use. (Refer to System Manual)
		Perform Quality Check	Use the Electronic Simulator to verify the cartridge-reading performance of new or replaced analyzers.
		Test-Method-Instrument Validation	Refer to "BayCare Laboratory Quality Management System: Test-Method-Instrument Procedure"
	Cartridge Test Cycle	Makes electrical contact with the cartridge Identifies the cartridge type Releases calibration fluid to the sensors (when applicable) Mixes sample and reagent (when applicable) Measures barometric pressure Heats the sensors to 37 ºC (when required by the test) Measures electrical signals generated by the sensors and calibration fluid (when applicable) Displaces the calibrant solution with sample (when applicable) Measures electrical signals generated by the sensors and sample Accepts the operator and patient ID's scanned or entered by the operator Accepts chart page information Calculates and displays results Stores results	
	Data Entry	Operator ID (Employee ID) Patient ID, Proficiency ID, or Simulator ID Cartridge Lot Number Control Lot Number Cal/Ver Kit Lot Number Comment codes for patient and control results (optional) Chart page (sample type, patient temperature, FIO2, and Free fields)	
	Storage of Results	5,000 test records	Set of Results Date-Time test was performed Cartridge Type Information entered by barcode scanner or keypad (Operator ID, Patient ID, Lot Numbers for Controls-Cartridges, Chart page data, and serial number of the electronic simulator) Serial number of analyzers

	Storage of Results (cont.)		Number of times the analyzer has been used Software versions installed in the analyzer Name of the analyzer's customization profile Quality Check Codes (problem with sample, calibration, sensors, and mechanical or electrical functions)
	Cartridge Packaging	Sealed in a paper pouch with a liquid impermeable inside pouch for protection during storage Labeling on the carton, box and pouch/portion pack identify (panel name, tests included in the panel, lot number, and expiration date of the cartridge) **DO NOT USE IF PACKAGE HAS BEEN PUNCTURED**	
	Cartridge Storage	2 - 8 ºC until expiration date on the cartridges 18 – 30 ºC Room Temperature before removing them from their sealed pouches (5 minutes for one cartridge, 1 hour for a box of 25 cartridges) – expiration date changes to 2 weeks (ACT, PT/INR, CHEM8, TNI, Crea) or 2 months (CG8+, CG4+, EG7+)	
	Control Storage	2 - 8 ºC until expiration date on the box	
	Calibration Verification Material	2 - 8 ºC until expiration date on the box	
4.0	**Procedure – Quality Control**		
	Newly Received Cartridges	Verify transit temperature using the 4-window temperature indicator strip Document lot number, temperature indicated on strip, operator ID, and date	
	Daily Analyzer Performance	Electronic Simulator (Internal) Performed every 8 hours for ACT and Blood Gas testing Performed daily for all other analytes	
	Refrigerator Storage	Verify refrigerator temperature, document, and perform corrective action (if applicable). Accomplished via automated temperature monitoring system or Min/Max thermometers. Temperature monitoring is reviewed and approved by Point of Care testing Team members.	
	Room Temperature Storage	Verify room temperature, document, and perform corrective action (if applicable) Accomplished via automated temperature monitoring system or Min/Max thermometers. Temperature monitoring is reviewed and approved by Point of Care testing Team members.	
	Thermal Probe Check	Performed twice a year – Refer to i-STAT Systems Manual	
	6 Month Software Update	Performed twice a year – Refer to Systems Manual. Liquid QC must be performed on all analyzers following software upgrade, and Cal/Ver material must be performed in addition for non-waived testing.	
	Performing Cal/Ver	Analyzer On Test Menu Administration Menu Quality Tests Menu	Press On/Off key Press Menu key Press 3 to select quality tests Press 3 to select Cal/Ver

	Performing Cal/Ver (cont.)	Quality Cal/Ver	
		Scan or Enter Operator ID	Press Scan or manually enter operator ID (5 to 7-digit team member number) – Press Enter
		Scan or Enter Cal/Ver Lot ID	Press Scan or manually enter the Cal/Ver lot ID – Press Enter
		Scan or Enter Cartridge Lot Number	Press Scan or manually enter the cartridge lot number – Press Enter
			Shake the ampule vigorously for 5 – 10 seconds (Hold the ampule at the top and bottom with forefinger and thumb)
			Protect fingers with gauze, tissue or glove, or use and ampule breaker to snap off the tip of the ampule at the neck
			Immediately transfer solution from the ampule into a capillary tube or syringe
			Immediately transfer the solution into the cartridge
			Immediately seal the cartridge
		Identifying cartridge – Please wait, cartridge locked	Insert cartridge into the analyzer
		i-STAT (Cartridge Panel number), Time to Results → Page, Cartridge locked	Chart page will be displayed automatically
		Cal/Ver Level (Lot Number) Scan or Enter Data	Scan or manually enter the Cal/Ver levels (1 thru 5) – Press Enter
		Field 1, 2, 3 → Page, Cartridge Locked	Press Enter to move thru all 3 fields
		Results	Test Options Cal/Ver (Next Level, Repeat Level, or History)
		Cartridge Locked message is removed	Remove cartridge and discard in a Sharps container
		Criteria for acceptability	All Cal/Ver values must be within manufacturer established ranges (on the VAS for that specific control and software version #)
		Note:	6-month Cal/Ver is not required for coagulation analytes (**ACT**, **INR**)
			To prove lower reportable range for **Lactate**, dilute the i-STAT Calibration Verification Level 5 to yield result near 0.35mmol/L.

	External Liquid QC Material	***PT/INR cartridge***- iSTAT PT/INR controls Level 1 & 2 ***ACT cartridge***- iSTAT ACT controls Level 1 & 2 ***Chem 8+ cartridge***- Tricontrols Level 1 & 3 **Creatinine cartridge –** i-STAT Tricontrols 1 and 3 ***CG8+/CG4+/EG7+ cartridge*** – i-STAT Tricontrols level 1 & 3	
		Waived	Validation upon implementation – Refer to "BayCare Laboratory Quality Management System: Test-Method-Instrument Verification". 2 levels – Each new lot of cartridges/shipment on a subset of analyzers 2 levels – If temperature at which the cartridges have been stored is in doubt 1 level – 1 cartridge from each refrigerated storage monthly
		Old lot/New Lot comparison	Document in the data manager (DE in Telcor QML) when QC is performed on a new lot # of cartridge and 30-day existing lot. Reviewed by the POCC - select correct comment, date/initials are automatically documented. Suitable reference material is purchased from the manufacturer for this purpose.
		Criteria for acceptability	All control values must be within manufacturer established ranges (on the VAS for that specific control and software version #)
		Non-Waived (Moderate – High Complexity)	Validation upon implementation (Accuracy, Precision, etc.) – Refer to "BayCare Laboratory Quality Management System: Test-Method-Instrument Verification". 2 levels – Each new lot of cartridges/shipment on a subset of analyzers, monthly, not to exceed 31 days of an existing lot of number – 2 levels of QC on every analyzer for each cartridge type tested 2 levels – If temperature at which the cartridges have been stored is in doubt
		Old lot/New Lot comparison	Document in the data manager (DE in Telcor QML) when QC is performed on a new lot # of cartridge and 30-day existing lot. Reviewed by the POCC - select correct comment, date/initials are automatically documented. Suitable reference material is purchased from the manufacturer for this purpose.
		Criteria for acceptability	All control values must be within manufacturer established ranges (on the VAS for that specific control and software version #)

	Performing Internal Electronic Simulator Test	Automatically activated when a cartridge is inserted after the customized interval is reached If "Electronic Simulator Fail" displays, do **NOT** perform patient testing Refer to Troubleshooting Section in the System Manual	
	Performing External Electronic Simulator Test	Analyzer On Test Menu Administration Menu Quality Tests Menu Scan or Enter Operator ID Scan or Enter Simulator ID Insert Simulator Contacting Simulator, Please wait… Time to Results bar Simulator Locked Result Screen: ID of Simulator, Date-time, Pass or Fail	Press On/Off key Press Menu key Press 3 to select quality tests Press 4 to select simulator Press Scan or manually enter operator ID (5 to 7-digit team member number) – Press Enter Press Scan or manually enter the simulator ID – Press Enter Remove the protective cover protecting the contact pads Insert the simulator straight into the analyzer Do **NOT** attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed If PASS is displayed, continue to use the analyzer If FAIL is displayed, do **NOT** perform patient testing Refer to Troubleshooting Section in the System Manual
	Performing Liquid QC for Blood Gas, Electrolyte, Metabolites, CG4+, Crea, or Chem 8+	Analyzer On Test Menu Administration Menu Quality Tests Menu Quality Tests Control Select Cartridge Select Fluid Scan or Enter Operator ID Scan or Enter Control Lot ID Scan or Enter Cartridge Lot Number	Press On/Off key Press Menu key Press 3 to select quality tests Press 1 to select control Select 2 Scheduled (for QC lockout) Select appropriate cartridge for QC Select appropriate QC level Press Scan or manually enter operator ID (5 to 7-digit team member number) – Press Enter Press Scan or manually enter the control lot ID – Press Enter Press Scan or manually enter the cartridge lot number – Press Enter Shake the ampule vigorously for 5 – 10 seconds (Hold the ampule at the top and bottom with forefinger and thumb) Protect fingers with gauze, tissue or glove, or use and ampule breaker to snap off the tip of the ampule at the neck Immediately transfer solution from the ampule into a capillary tube or syringe Immediately transfer the solution into the cartridge

	Performing Liquid QC for Blood Gas, Electrolyte, Metabolites, CG4+, Crea, or Chem 8 (cont.)		Immediately seal the cartridge
		Identifying cartridge – Please wait, cartridge locked	Insert cartridge into the analyzer
		i-STAT (Cartridge Panel number), Time to Results → Page, Cartridge locked	Chart page will be displayed automatically
		Control (Lot Number) Scan or Enter Data	Scan or manually enter the control level (such as 1, 2, 3) – Press Enter
		Field 1, 2, 3 → Page, Cartridge Locked	Enter comments (optional) and/or Press Enter to move thru all 3 fields
		Results	Test Options Control (Next Level, Repeat Level, or History)
		Cartridge Locked message is removed	Remove cartridge and discard in a Sharps container
	Performing Liquid QC for Hematocrit	Analyzer On	Press On/Off key
		Test Menu	Press Menu key
		Administration Menu	Press 3 to select quality tests
		Quality Tests Menu	Press 1 to select control
		Quality Tests Control	Select 2 Scheduled (for QC Lockout)
		Select Cartridge	Select appropriate cartridge for QC
		Select Fluid	Select appropriate QC level
		Scan or Enter Operator ID	Press Scan or manually enter operator ID (5 to 7-digit team member number) – Press Enter
		Scan or Enter Control Lot ID	Press Scan or manually enter the control lot ID – Press Enter
		Scan or Enter Cartridge Lot Number	Press Scan or manually enter the cartridge lot number – Press Enter
			Gently invert the ampule to mix the solution
			Protect fingers with gauze, tissue, or glove, or use and ampule breaker to snap off the tip of the ampule at the neck
			Immediately transfer solution from the ampule into a capillary tube or syringe
			Immediately transfer the solution into the cartridge
			Immediately seal the cartridge
		Identifying cartridge – Please wait, cartridge locked	Insert cartridge into the analyzer
		i-STAT (Cartridge Panel number), Time to Results → Page, Cartridge locked	Chart page will be displayed automatically
		Control (Lot Number) Scan or Enter Data	Scan or manually enter the control level (such as 1, 2, 3) – Press Enter

	Performing Liquid QC for Hematocrit (cont)	Field 1, 2, 3 → Page, Cartridge Locked Results Cartridge Locked message is removed	Enter comments (optional) and/or Press Enter to move thru all 3 fields Test Options Control (Next Level, Repeat Level, or History) Remove cartridge and discard in a Sharps container
	Performing Liquid QC for ACT and INR	Reconstituting Control material Analyzer On Test Menu Administration Menu Quality Tests Menu Quality Tests Control Select Cartridge Select Fluid Scan or Enter Operator ID Scan or Enter Control Lot ID Scan or Enter Cartridge Lot Number	Bring Calcium Chloride reconstituting diluent to room temperature for a minimum of 45 minutes Control solution **MUST** be used immediately (within 30 seconds) after completing the reconstitution and mixing steps Remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid. Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial. Allow the vial to sit at room temperature for 1 minute Mix the contents of the vial by swirling gently for 1 minute. Invert slowly for 30 seconds. Using a plastic transfer pipette, syringe, or capillary tube with no anticoagulant Immediately transfer the solution from the vial into the ACT cartridge Immediately seal the cartridge and insert it into an analyzer Press On/Off key Press Menu key Press 3 to select quality tests Press 1 to select control Press 2 scheduled (for QC Lockout) Select appropriate cartridge for QC Select appropriate QC level Press Scan or manually enter operator ID (5-7-digit team member number) – Press Enter Press Scan or manually enter the control lot ID – Press Enter Press Scan or manually enter the cartridge lot number – Press Enter

	Performing Liquid QC for ACT and INR (continued)		Mix the contents of the vial by swirling gently for 1 minute. Invert slowly for 30 seconds. Using a plastic transfer pipette, syringe, or capillary tube with no anticoagulant Immediately transfer the solution from the vial into the ACT cartridge
		Identifying cartridge – Please wait, cartridge locked	Immediately seal the cartridge and insert it into an analyzer
		i-STAT (Cartridge Panel number), Time to Results → Page, Cartridge locked	Chart page will be displayed automatically
		Control (Lot Number) Scan or Enter Data	Scan or manually enter the control level (such as 1, 2, 3) – Press Enter
		Field 1, 2, 3 → Page, Cartridge Locked	Enter comments (optional) and/or Press Enter to move thru all 3 fields
		Results	Test Options Control (Next Level, Repeat Level, or History)
		Cartridge Locked message is removed	Remove cartridge and discard in a Sharps container
	Documentation of QC	QC is retained in Telcor QML Data Management System. POC Coordinator at the respective facility reviews and approves both the new lot/shipment and the 30-day QC on an existing cartridge lot. This system will document both who reviewed the QC and who performed the QC.	
	Corrective Action	Document in Telcor QML Data Management System if this is repeated QC for failed QC. Do **NOT** report patient results if the QC is not within acceptable limits	
5.0	**Procedure – Sample Collection, Type, Preparation for Testing**		
	Sample Collection **Lancets**	Venipuncture – Refer to "BayCare Laboratory Collections: Collection of a Blood Sample – Venipuncture". Capillary Puncture – Refer to "BayCare Laboratory Collections: Collection of a Blood Sample – Capillary". Only auto-disabling single-use fingerstick devices are utilized for collection of samples – PT/INR cartridge. Arterial Puncture – Refer to "BayCare Laboratory Collections: Collection of a Blood Sample – Arterial" Gently mix blood (anticoagulated or not) immediately to avoid clotting (Blood collection tube 10 times, Syringes rolled between the palms for at least 5 seconds) Discard the first 2 drops, if using a syringe Avoid exposure to air for pH, pO2, pCO2, and TCO2 (Test immediately if the sample is drawn into a blood collection tube, expel any air bubbles if the sample is drawn into a syringe) Line draws- For line draws, the line should be flushed with 5mL of saline and the first 5 mL of blood or six dead space volumes should be discarded.	

	Sample Collection Limitations	Drawing from an arm with an I.V. Line (dilution of sample) Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid Muscle activity such as clenching and unclenching the fist, which may increase potassium results Reduce hemolysis by allowing residual alcohol to dry over the puncture site or discarding a sample from a traumatic draw which will cause an increase in potassium results and a decrease in calcium results Collect blood collection tubes in the following sequence to avoid interference due to carry-over of additive from one tube to another (No additive, Citrate, Heparin, EDTA, and Oxalate) If a citrate tube is drawn, draw a 5 mL plain discard tube prior to collection of the heparin tube **Lactate samples** – to prevent changes during collection, venous samples should be obtained without the use of a tourniquet, or immediately after tourniquet is applied. Collection of additional tubes that do not require a heparin additive should be obtained from a second collection. **Lactate samples** should be analyzed immediately, or within 10 minutes of collection – lactate value increases by as much as 70% within 30 minutes as a result of glycolysis	
	Sample Type	Blood gases, Electrolyte, Chemistry and Hematocrit Tests	Syringe, pre-heparinized syringe, lithium heparin tube
		Chem 8+ Cartridge Lactate (ED Stat Lab)	Heparinized whole blood collected in evacuated tubes containing lithium heparin, if the tubes are filled to capacity
		*Chem 8+ Cartridge for Isolation	Treated as a moderate complexity test – must collect in syringe – load direct to cartridge
		Coagulation Tests	Plastic collection device (syringe or collection tube) containing **NO** anticoagulant, clot activators, or serum/plasma separators. Any transfer device **MUST** be plastic (dispenser, capillary tube, pipette, or syringe)
		INR Testing	Venous or capillary, DO NOT WIPE AWAY the 1st drop of blood.

	Time to Test	Syringe Lactate pH, pCO2, pO2, TCO2, iCa Coagulation HCT, and other Analytes	Immediately Immediately Within 10 minutes Immediately Within 30 minutes
	Sample Transfer Devices	A dispenser can be used to avoid the use of needles when transferring a blood sample from a blood collection tube (capillary tubes, 1 cc syringe with no smaller than a 20-gauge needle) **DO NOT USE** dispensers that would introduce air into the sample when Ionized Calcium, pH, pCO2, or TCO2 are being measured	
	Preparation for Testing	Select the cartridge for the tests requested Allow cartridge to come to room temperature (18 – 30 ºC) Analyzer needs to be at room temperature (18 – 30 ºC) Remove cartridge from protective pouch Do **NOT** contaminate the contact pads with fingerprints or talc from gloves Do **NOT** apply pressure to the central area of the label Do **NOT** block the air vent Do **NOT** use a cartridge on which blood or any other fluid has spilled	
6.0	**Procedure – Patient Testing**		
	Filling and Sealing Cartridge using Transfer Device	Place the cartridge on a flat surface Direct the tip of the syringe, capillary tube, or dispenser into the sample well Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label Leave some sample in the sample well Fold the snap closure over the sample well Press the rounded end of the closure until it snaps into place	
	Entry of Information	Analyzer Off Analyzer On Press 2 Press Scan Press Enter Press Scan Press Enter Press Scan Press Enter	Press On/Off Key Display Logo followed by Test Menu Press Menu key or turn Analyzer Off, then back On Select i-STAT cartridge Scan the Operator ID (5-7-digit team member ID) or manually enter Scan the patient bar-coded ID armband to enter the Patient ID (financial number) Scan the Lot Number of the cartridge or manually enter

	Cartridge Entry	Align the cartridge with the contact pads facing up and toward the cartridge port Push the cartridge slowly and smoothly into the cartridge port until it clicks into place Do **NOT** attempt to remove the cartridge while the message "Cartridge Locked" prompt is on the screen	
	Cartridge Identification	Analyzer Displays	Identifying Cartridge please wait i-STAT (Cartridge Panel Number) Time to Results → Page Cartridge Locked
	Chart Page Entry (optional)	Press ID Sample Type Field 1 Field 2 Field 3 CPB	→ Scan or enter data – Press Enter Choose sample type – Press Enter Enter comments and/or Press Enter Enter comments and/or Press Enter Enter comments and/or Press Enter Enter YES for hematocrit results, NO if hematocrit is not requested – Press Enter
	Results Ready	Results Page Not on Results Page	Analyzer unlocks the cartridge and is ready for another test Press → to return to results page
		Comments	Scan or manually enter a comment code
	Cartridge Removal	When results are displayed, pull the cartridge straight out of the analyzer Dispose of the cartridge in a Sharps container	
	Disinfection	Many testing locations do not have the i-STAT analyzer in contact with the patient. However, in those testing locations that do have the portable i-STAT in close proximity to the patient, the i-STAT analyzer must be disinfected after each patient utilization with the analyzer. This will be completed with the BayCare approved sanitizer/disinfectant.	
7.0	**Procedure – Results**		
	Results Display	Numerical concentration values in the units selected for the analyte	
	Data Transfer	For the serial downloader, check that the green power light is on. While the i-STAT is turned OFF, place the infrared window of the i-STAT between the arms of the downloader, a red light will turn on and data will transmit. OR For the recharger downloader, place the analyzer in the cradle. Do not move analyzer while "Communication in Progress" is displayed.	

	Reference Intervals (Normal)	On the instrument screen, bar graphs depict the values in relation to reference intervals defined for the analyte (Exception: Blood Gas and Coagulation) **Reference Intervals indicated on the bar graphs by tic marks. Results outside the respective normal reference range for the analyte are indicated with (↑), above, or (↓), below.** Refer to "i-STAT Analyte Chart" for the normal reference ranges for each analyte.
	Interfering Substances	**ACT** -Collection in glass may prematurely activate coagulation resulting in accelerated clotting times. Analyzer must remain level during testing, if not ACT result may be affected by more than 10%. Any platelet dysfunction or coagulopathy may affect ACT results. **Chloride-**Hemodilution of plasma by more than 20% w/solutions that do not match ionic properties of plasma (such as ones to prime CP bypass pumps) **Glucose** -Use of drug Hydroxyurea cause significant errors. PO2 >20 mmHg may decrease glucose. Thiocyanate falsely lowers glucose. 37.5 mmol/dL Bromide may lower Glu by 30 mg/dL. **HCO3**-Exposure of sample to air causes HCO3 to be under-estimated. **HCT**- Grossly elevated WBC may increase Hct. Abnormally high lipids may increase hematocrit. Hematocrit results affected when total protein level is <6.5 or >8.0 g/dL. **Ionized Ca-** Hemodilution of plasma by more than 20% w/solutions that do not match ionic properties of plasma (such as ones to prime CP bypass pumps) **pCO2**- Exposure of sample to air cause PCO2 to decrease. **PT/INR**- Analyzer must remain level. Cubicin can cause a false prolongation of (PT) & elevation of INR. Capillary testing DO NOT wipe away first drop of blood **pH**- Hemodilution of plasma by more than 20% w/solutions that do not match ionic properties of plasma (such as ones to prime CP bypass pumps). Exposure of sample to air causes pH to increase. **PO2**- Exposure of sample to air will increase PO2 when below 150 mmHg, & decrease PO2 when above 150 mmHg **Sodium** - Hemodilution of plasma by more than 20% w/solutions that do not match ionic properties of plasma. **Lactate –** Bromide at 37.5 mmol/L and above will cause a decreased lactate result Glycolic Acid (product of ethylene glycol metabolism) at a concentration of 10.0 mmol/L and above will cause an increased lactate result. Use another method. Hydroxyurea use of this drug at concentration 0.92 mmol/L and higher will cause an increased lactate result. Use another method. **Creatinine** – Hydroxyurea: use of this drug at concentration 0.92 and higher will cause an increased creatinine result. Use another method. Bromide use at 2.5mmol/L and above will cause an increased creatinine result. Use another method

	Interfering Substances Cont.	Sodium Thiosulfate use at 16.7mmol/L and above will cause an increased creatinine result. Glycolic Acid use at 10.0mmol/L and above will cause a decreased creatinine result. Use another method.	
	Reportable Range (AMR)	Refer to "i-STAT Analyte Chart" for reportable ranges, (analytical measurement range or AMR), for each analyte.	
	Critical Values	Critical values require immediate attention. Results that flag as a critical value in Cerner/Beacon are communicated directly to the licensed caregiver at the time of testing Refer to **"**i-STAT Analyte Chart" for applicable critical values for each analyte.	
	Flags	>	Result above the reportable range
		<	Result below the reportable range
		< >	Result is dependent on another test that has been flagged (Displayed for TCO2, pH, pCO2, HCO3, Anion Gap, Base Excess, and sO2 if the TCO2 is outside the reportable range) If a Sodium result of > 180 is displayed, the calculations for Potassium, Chloride, BUN/Urea, and Hematocrit, which depend upon the Sodium measurement, will be flagged<>.
		***	Signals are uncharacteristic for a particular sensor – Retest sample
		↑	Result above the respective normal range for the analyte
		↓	Result below the respective normal range for the analyte
	Documentation of Results	Results interface through the i-STAT data management system, Telcor, and finally interface into Cerner (Beacon) for the patient EMR.	
8.0	**Procedure – Maintenance**		
	As Needed	Refer to Systems manual for instructions Drying a Wet analyzer or downloader Cleaning the analyzer and downloader Removing and replacing batteries Removing and replacing the rechargeable battery	
9.0	**Principle**	Micro-fabricated thin film electrodes or sensors are assembled in unit-use cartridges containing: Calibrant solution in cartridges with sensors for blood gases, electrolytes, chemistries, and hematocrit Reagents in cartridges with sensors for coagulation Sample handling system Waste chamber Array of miniaturized sensors Conductive pads to make electrical contact with the analyzer Heating elements in cartridges requiring thermal control at 37 ºC	

10.0	**Related Documents**	"Moderate Complexity Testing Procedure" "BayCare Laboratory Quality Management System Manual: Test-Method-Instrument Verification and Reference Intervals Procedure " BayCare Laboratory Quality Management System Manual: Validation Chart – Reference Materials" "BayCare Laboratory Quality Management System Manual: Critical Values/Tests Procedure" "i-STAT Analyte Chart" "i-STAT Training – Skills Checklist" "i-STAT Super-user Training Checklist" "i-STAT Performance Validation Checklist" – initial, 6 month, 1year-annual
11.0	**References**	i-STAT 1 Systems Manual, i-STAT Corporation, New Jersey (Current Edition)
12.0	**Attachment**	N/A
13.0	**Author**	Written by Tom Miller, St. Joseph's Hospital Point of Care Coordinator on Dec. 16, 2006 Revised by Karen Noyce, SFB Laboratory Manager, on Oct. 1, 2008 Revised by Camille Smith, Mease Countryside Point of Care Coordinator on October 1, 2009. Added new facility on December 2, 2009. Added new Outpatient department on April 28, 2010 Revised scope by Debbie Lettau on December 21, 2010 Revised for reference values, reportable range, and critical ranges, Appendix A, by Tom Miller, St. Joseph's Hospital Point of Care Coordinator, on Sept. 19, 2011 Revised by Bob Ferguson, Lab Manager, November 25, 2011 Revised TNI control storage by Thomas H Miller, BayCare Regional POC Manager on 6-13-2013. Revised for Cal/Ver procedure, new lot/old lot comparison, timing of QC and Cal/Ver performed after CLEW software upgrades, and added a disinfection section by Thomas H Miller, BayCare Regional POC Manager on 8/27/2013. Added hyperlinks and revised cartridge storage (3.0), external Liquid QC material and Performing Liquid QC (4.0), Sample collection and Sample Collection Limitations (5.0), and Interfering Substances (7.0) to add Lactate testing performed on the CG4+ cartridge by Thomas H Miller, BayCare Regional POC Manager on September 30, 2014. Added EG7+ cartridge for WHH and removed some discontinued i-STAT QC from section (4.0) Quality Control and added EG7+ cartridge for WHH to section (3.0) Supplies by Thomas H Miller, BayCare Regional POC Manager on November 20, 2015. Removed sodium heparin as an acceptable anticoagulant for i-STAT sample collection due to a change per the manufacturer, and updated section (10) Related Documents by Thomas H Miller, BayCare Regional POC Manager on December 7, 2016.

		Revised Section 1.0 to better define the limitation of the PT/INR cartridge to define utilization is only allowed for use with Coumadin/Warfarin anticoagulant, and revised Section 4.0 remove reference of CDS and added EVAS system set up by Thomas H Miller, BayCare Regional Point of Care Manager on January 16, 2018. Revised Section 7.0 to add Interfering Substances for Creatinine by Thomas H Miller, BayCare Regional Point of Care Manager on March 12, 2018. Revised Section 5.0 – (Lancets) to include lancets must be single-use auto Disabling, Section 1.0 to define limitation of ACT cartridge use is only for patients on Heparin anticoagulant, Section 5.0 updated Sample Types, Section 4.0 (Performing Cal/Ver) to include means of obtaining lower reportable range for Lactate during Calibration Verification, and Section 4.0 – QC Documentation. Removed all references to CLEW, updated disposal of cartridges into Sharps container instead of biohazardous waste by Thomas H Miller, BayCare System Point of Care Manager on March 19, 2019. Revised Section 3.0 (Cartridge Storage) to remove EC4+, and G3+; and add Creatinine only. Revised Section 4.0 (Refrigerator Storage and Room Temperature Storage) to include automated temperature monitoring in addition to Min/Max thermometers; and (External Liquid QC Material) to remove G3+, EC4+, E3+, and add Creatinine only cartridges. Revised Section 5.0 (Sample Type) to remove capillary sample for Chem 8 Cartridge, renamed EVD to Isolation, and INR sample to include venous as an additional option by Thomas H Miller, BayCare System Point of Care Manager on September 2, 2020. Revised Section 4.0 (Performing Cal/Ver – Note section) to update how to prove to a lower Reportable Range for Lactate due to the transition from the Vista to the Alinity instrumentation by Thomas H Miller, BayCare System Point of Care Manager on August 15, 2022. Revised Section 4.0 – Performing Cal/Ver, - External Liquid QC Material - Section 5.0 – Sample Type – Time to Test to remove mention of Troponin I since testing removed from instrument by Thomas H Miller, BayCare Point of Care System Manager on May 18, 2023.
14.0	**Approval**	See Annual Review Document